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510(k) Summary

I-1.ADMINSTRATIVE INFORMATION

I-1.1 Name and address

Submitted by: Survivalink Corporation
5430 Feltl Road
Minneapolis, MN 55343

Contact Person: Sew-Wah Tay, Ph.D.
Telephone No.: 612-939-4181 ext. 142
Facsimile No.: 612-939-4191

Date Prepared: May 5, 1997

I-1.2 Device Name

Common or Usual Name: Automated External Defibrillator (AED)
Device Name: FirstSave™ Automated External Defibrillator

I-1.3 Classification

Class III MKJ (AED)

Classification Name: a) DC defibrillator
21CFR§870.5300; Class III
b) Cardiac Monitor (Cardiotachometer and Rate Alarm)
21CFR§870.2300; Class II

I-1.4 Applicant

Applicant's Name: Survivalink, Corporation
5430 Feltl Road
Minneapolis, MN 55343

I-2.PREDICATE DEVICES

FirstSave STAR Biphasic AED, models 9200 and 9210 (K982264)

I-3.INDICATION FOR USE

The Survivalink's FirstSave™ Biphasic AED is designed for emergency treatment of cardiac arrest by trained personnel to terminate potentially fatal arrhythmias for patients over 8 years old. The user assesses the patient's condition and confirms that the patient is unconscious, pulseless and is not breathing prior to use of the device.

I-4 DEVICE DESCRIPTION

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The FirstSave STAR Biphasic AED is a biphasic portable battery operated semi-automatic low power DC defibrillator. The device's diagnostic algorithm analyzes the patient's cardiac rhythm to determine shockable versus non-shockable EKG rhythm. The operator then pushes the button to deliver the defibrillation shock. The FirstSave STAR Biphasic feature includes:

- Lithium battery
- Single user button for Rescue or Resume
- LED diagnostic panel
- Non-volatile status indicator
- Voice prompts
- Biphasic truncated exponential defibrillation waveform

I-5. SUBSTANTIAL EQUIVALENCE

The Company's modified FirstSave STAR Biphasic covered by this submission is substantially equivalent to other legally marketed semi-automatic low power DC defibrillators. Specifically, the FirstSave STAR Biphasic is substantially equivalent to the Survivalink FirstSave STAR Biphasic previously cleared under the 510(k) K982264. The FirstSave STAR Biphasic has the same general indication for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate devices. The minor differences this device and its predicate devices do not raise new questions of safety or efficacy.

I-6. PERFORMANCE DATA

The performance test data is provided in the 510(k) submission. The performance data demonstrate that the device complies with the applicable sections of AAMI DF39-1993, IEC 601-2-4 and AAMI DF2-1996.

Tests results include rhythm detection, EMC, charge time, pulse shape, battery capacity, defibrillation recovery, design verification and validation data for hardware and software incorporated into the FirstSave STAR Biphasic. Environmental tests performed on the finished device include foreign object and water penetration, drop, vibration, humidity, altitude and temperature.

Test data demonstrate that the safety and effectiveness of the Modified FirstSave STAR Biphasic in this submission is substantially equivalent to the FirstSave STAR Biphasic (K982264).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2001

Sew-Wah Tay, Ph.D.
V.P. of Regulatory Affairs and QA
Survivalink Corporation
5420 Feltl Road
Minneapolis, MN 55343

Re: K010214
Trade Name: FirstSave™ STAR Biphasic™ AED
Regulatory Class: III (three)
Product Code: MKJ
Dated: January 22, 2001
Received: January 23, 2001

Dear Dr. Tay:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number; K010214

Device Name: FirstSave STAR Biphasic AED

Indication for Use

The FirstSave STAR Biphasic AED semi-automatic external defibrillator is designed for emergency treatment of cardiac arrest patients by trained personnel. The user assesses the patient's condition and confirms that the patient is unconscious, pulseless and is not breathing prior to use of the device. The FirstSave STAR Biphasic AED is intended to be used on patients older than eight years[1].

Division of Cardiovascular & Respiratory Devices
510(k) Number K010214

[1] American Heart Association "Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care" Circulation Supplement Vol 102(8) Aug. 2000.